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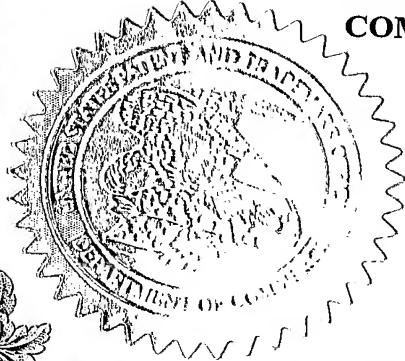
APPLICATION NUMBER: 60/598,835

FILING DATE: August 05, 2004

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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22264 U.S. PTO
60/598835
080504

| INVENTOR(S) | | |
|--|--|---|
| Given Name (first and middle [if any]) ELAN | Family Name or Surname ZIV MD | Residence (City and either State or Foreign Country) RAMAT GAN, ISRAEL |
| Additional inventors are being named on the _____ separately numbered sheets attached hereto | | |
| TITLE OF THE INVENTION (500 characters max) A DISPOSABLE DEVICE FOR THE TREATMENT & PREVENTION OF URINARY INCONTINENCE DURING PHYSICAL ACTIVITY IN FEMALES | | |
| Direct all correspondence to: CORRESPONDENCE ADDRESS | | |
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| ENCLOSED APPLICATION PARTS (check all that apply) | | |
| <input checked="" type="checkbox"/> Specification Number of Pages 8 | <input type="checkbox"/> CD(s), Number _____ | |
| <input checked="" type="checkbox"/> Drawing(s) Number of Sheets 7 | <input type="checkbox"/> Other (specify) _____ | |
| <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 | | |
| METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT | | |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. | FILING FEE Amount (\$) | |
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Respectfully submitted,

[Page 1 of 2]

Date **25.7.04**SIGNATURE 15.07

REGISTRATION NO. _____

TYPED or PRINTED NAME D2. ELAN ZIV MD

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)**80**

Complete if Known

| | |
|----------------------|--------------|
| Application Number | |
| Filing Date | 25.7.04 |
| First Named Inventor | Dr. ELAN 21V |
| Examiner Name | |
| Art Unit | |
| Attorney Docket No. | |

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3. ADDITIONAL FEES

| Large Entity | Small Entity | Fee Description | Fee Paid |
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| 1051 130 | 2051 65 | Surcharge - late filing fee or oath | |
| 1052 50 | 2052 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 130 | 1053 130 | Non-English specification | |
| 1812 2,520 | 1812 2,520 | For filing a request for ex parte reexamination | |
| 1804 920* | 1804 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 1,840* | 1805 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 110 | 2251 55 | Extension for reply within first month | |
| 1252 420 | 2252 210 | Extension for reply within second month | |
| 1253 950 | 2253 475 | Extension for reply within third month | |
| 1254 1,480 | 2254 740 | Extension for reply within fourth month | |
| 1255 2,010 | 2255 1,005 | Extension for reply within fifth month | |
| 1401 330 | 2401 165 | Notice of Appeal | |
| 1402 330 | 2402 165 | Filing a brief in support of an appeal | |
| 1403 290 | 2403 145 | Request for oral hearing | |
| 1451 1,510 | 1451 1,510 | Petition to Institute a public use proceeding | |
| 1452 110 | 2452 55 | Petition to revive - unavoidable | |
| 1453 1,330 | 2453 665 | Petition to revive - unintentional | |
| 1501 1,330 | 2501 665 | Utility issue fee (or reissue) | |
| 1502 480 | 2502 240 | Design issue fee | |
| 1503 640 | 2503 320 | Plant issue fee | |
| 1460 130 | 1460 130 | Petitions to the Commissioner | |
| 1807 50 | 1807 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 180 | 1806 180 | Submission of Information Disclosure Stmt | |
| 8021 40 | 8021 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 770 | 2809 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 770 | 2810 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 770 | 2801 385 | Request for Continued Examination (RCE) | |
| 1802 900 | 1802 900 | Request for expedited examination of a design application | |

Other fee (specify)

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SUBTOTAL (3) (\$)

(Complete if applicable)

SUBMITTED BY

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A DISPOSABLE DEVICE FOR THE TREATMENT AND PREVENTION OF URINARY INCONTINENCE DURING PHYSICAL ACTIVITY IN FEMALES

The present invention relates generally to the field of treatment of urinary incontinence in female patients. More specifically, the present invention relates to a disposable device for use in the treatment of severe urinary incontinence, or incontinence during high impact physical activity, in women. The invention describes a vaginal disposable device which is inserted and removed in a no-self-touch technique, by the patient herself, using a disposable applicator.

10

Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

Background of the Invention

Urinary incontinence is a widespread problem among females. It is estimated that up to 50% of women occasionally leak urine involuntarily, and that approximately 25% of women will seek medical advice at some point in order to deal with the problem. Stress incontinence, the most common type of urinary incontinence, refers to the involuntary loss of urine resulting from abdominal pressure rise, occurring during exercise, coughing, sneezing, laughing, etc. When stress incontinence occurs, it is usually the result of the abnormal descent of the urethra and bladder neck below the level of the pelvic floor. While many different factors may contribute to the development of stress incontinence, it is most prevalent among women ages 35-65 and those who have had multiple vaginal deliveries. Stress incontinence is both aggravating and unpleasant for women, and it can also be embarrassing. Many women wear sanitary pads or diapers in order to deal with incontinence, though this is not a real solution to the problem and it can be very inconvenient and unreliable. Surgical treatment may involve securing the paraurethral tissues to the periosteum of the pubic bone or the rectus fascia in order to elevate the bladder neck above the pelvic floor and thereby distribute pressure equally to the bladder, the bladder neck, and the mid-urethra. Recently, a procedure known as "TVT" ("Tension Free Vaginal Tape") was developed, in which a mesh tape is implanted underneath mid-urethra, creating a hammock on which the urethra may kink during physical effort.

A disposable device for treatment & prevention of female urinary incontinence during physical activity
Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

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However, surgery is only suitable for severe cases, and the majority of women experiencing incontinence do not need surgical solutions.

One modality of non-surgical treatment involves the use of devices that are inserted into the vagina, either by a medical practitioner or by the woman herself. Most devices are
5 designed to apply pressure against the bladder neck so as to inhibit or completely block the flow of urine through the urethra. A variety of such devices are known in the art. For example, refer to U.S. Patent No. 5,618,256 to Reimer, entitled, "Device for Arrangement in the Vagina for Prevention of Involuntary Urination with Females and an Applicator for use in Insertion of the Device;" U.S. Patent No. 5,785,640 to Kresch, entitled "Method
10 for Treating Female Incontinence;" U.S. Patent No. 4,920,986 to Biswas, entitled, "Urinary Incontinence Device;" U.S. Patent 5,417,226 to Juma, entitled, "Female Anti-Incontinence Device;" U.S. Patent No. 5,386,836 to Biswas, entitled, "Urinary Incontinence Device;" and U.S. Patent No. 5,007,894 to Enhoring, entitled, "Female Incontinence Device."
15 A more pronounced problem is the urinary incontinence which is related to high impact physical activity, such as jogging, spinning, daily gym activity, athletics, etc. This is a very special sub-entity of the profession, as most of the sufferers are young-middle aged active women who have to stop or reduce such activities. Most conservative treatments fail to supply such protection against sports incontinence, and in the art there is only one
20 group of conservative devices which might be able to block the urethra and therefore block any leakage altogether. This is the group of "urethral inserts" which are inserted into the urethra by the woman, after completely emptying her bladder, and serves until removal for the next voiding. Such devices are most unpopular as the woman has to insert it herself, the procedure is uncomfortable, sometimes painful, and side effects are
25 bleedings and urinary tract infections.

The existing non-surgical incontinence devices suffer from numerous drawbacks:

- A number of devices are constructed so as to completely block the urethra and thus they need to be removed or collapsed in order to allow the woman to urinate, an inconvenience for the woman wearing the device.
30

- To overcome this drawback, vaginal devices have been developed having specialized shapes that do not completely block the bladder neck. These devices tend to be large, uncomfortable, and intrusive. They also tend to cause irritation or soreness to the vagina.
- 5 • Such devices are expensive to manufacture, and therefore, they are designed to be re-usable and/or to remain in the vagina for an extended period of time. Such devices are normally made from large bodies of resilient material, such as plastic or hard rubber, in order to preserve their functioning for the required amount of time.
- 10 • Most devices known in the art also tend to be difficult or painful to insert and/or remove. In order to correctly inhibit urine flow, the device needs to be properly positioned in the vaginal canal. As stated previously, a doctor may be required to properly position the device.
- 15 • In cases where a doctor has to insert the device, the device is adapted for remaining in the vagina for a prolonged period of time. When positioned in the vagina for an extended period of the time, the device may cause vaginal infections, necrosis, or bleeding.
- 20 • The device may block or inhibit the flow of normal body secretions through the vagina, and may cause inflammation of the vagina and a foul-smelling discharge.
- In cases where the device is designed to be inserted by the woman herself, the device often has to be removed, cleaned, and then re-inserted after a predetermined number of hours.

All vaginal devices so far described or marketed have at least one of the limiting features described above. No vaginal device for controlling urinary incontinence has so far been
25 successfully marketed and used by the woman herself. There is a need for a device for controlling involuntary urination that is disposable, easy and comfortable for a woman to use, that works effectively and reliably, and that is completely sanitary and hygienic.

The Invention

The present invention provides a device for the treatment of severe urinary incontinence during high impact physical activity in females. The device of the present invention is adapted to be disposable, worn only for several hours and then discarded and replaced

5 with a new device (if needed). The device of the present invention is simple and easy to use, and is inserted effortlessly in the same user-friendly and familiar manner that a tampon is inserted into the vagina during menstruation. As opposed to large and intrusive devices of the prior art, the device of the present invention is comfortable, and easy to wear.

10 When involuntary urination occurs, it is usually the result of the abnormal descent of the bladder neck and the urethra into a low position, away from the intra-abdominal pressure system. This "hypermobility" is the result of some injury to the support mechanism which normally keeps the urethra and the bladder neck in a raised position, along the backside of the pubic bone. The lowering of the bladder neck and the urethra that occur, 15 for example, when a woman coughs, sneezes, laughs, or performs physical activity, causing involuntary leakage of urine. The device of the present invention is designed to provide a shelf-like support to the urethra, thereby elevating intra-urethral pressure whenever the urethra descends momentarily, so as to prevent the leakage of urine. The device maintains constant low external pressure against the urethra, when there is a rise in 20 abdominal pressure.

The concept behind this kind of a device, intended for prevention of high impact physical activity urinary leakage, is that such activity is of relatively short duration, hence there is no necessity to allow for unobstructed urinary flow. It is therefore acceptable to allow some low external pressure from the vagina on mid urethra in order to elevate intra-urethral pressure. Unlike devices which should stay in the vagina for longer periods, and 25 allow for unobstructed urinary flow, this device might cause some voiding difficulties if urination is attempted while using it.

30 The present invention relates to a disposable device for the prevention of involuntary urination in females, adapted for being inserted into the vagina, comprising;

(a) an internal support structure

(b) a cover covering said internal support structure and comprised of a flexible material, and;

(c) an applicator coupled to the internal support structure and the cover for facilitating insertion of the device into the vagina;

5 The main device and the cover are adapted for forming a cradle support for the mid-urethra following insertion of the device into the vagina so as to prevent involuntary urination.

The invention will now be described with reference to accompanying drawings:

10 FIG. 1A is a side view of the internal support structure.
FIG. 1B is a top view of the internal support structure
FIG. 1C is a perspective view of the internal support structure
FIG. 2A is a side view of the internal support structure with urethral support ring
FIG. 2B is a cut view of the internal support structure with urethral support ring
15 FIG. 2C is a top view of the internal support structure with urethral support ring
FIG. 2D is an isometric view of the internal support structure with support ring
FIG. 3A is a perspective view of the covering
FIG. 3B is a perspective view of the main device inside the covering.
FIG. 4 is a perspective view of the applicator.
20 FIG. 5 is a sectional view of the invention within the applicator
FIG. 6 is a side view of the female pelvis.

The core of the device is a one prolonged embodiment (FIG 1A) which has three distinct parts:

25 1. A top section (6) which serves as the "anchoring" element, for stabilizing the device within the vagina,
2. A bottom section (10) which serves as the "supporting" element, generating mid-urethral support,
3. An intermediate section (8) which connects top & bottom elements. This section
30 might be of various widths – a wide continuation between two sections, or a very thin one for extra flexibility.

Each element of the device (FIG 1A+B+C) has 4 flexible arms. These arms of the anchoring element (12), force the device to remain in situ within the vagina, unable to move inwards or outwards, or to rotate. This occurs as a result of the special tendency of vaginal walls to collapse and form an occluded lumen. The flexible arms of the device
5 cause "tenting" of the walls on top of them with resultant sagging of the walls around the intermediate section, thereby stabilizing the device. The arms of the supporting element (14) cause elevation of the tissues around mid-urethra, acting as a hammock.

A circular ring (13) is attached to the four supporting arms, as shown in figures 10 2A+B+C+D. Attachment of the rings to the body of the device may be while using a notch (15) or by any other mean of connection. The ring itself might be of constant diameter at its entire length, or different diameters and widths or flattening at some points, such as the area between the arms, for better wider support under mid-urethra. The ring between the arms of the device serve as an external way to stop or reduce urinary leakage for a predefined period of time – such as the time of jogging, between two consecutive urinations. Dependent on the level of external under-urethral pressure, there 15 might be full or partial occlusion of the urethra for a limited period of time.

The cover (FIG 3A) is made of a flexible smooth mesh material (16) designed as small sack with a string (18). FIG 3B shows the device (20) within the tightly closed mesh cover (22). The cover allows for:

- 20 • Reduction of the friction between vagina and the device during insertion & removal.
- Reduction of the friction between the applicator and the device during insertion.
- Pulling the string causes straightening of the cover, straightening of the vaginal walls, allowing for an easy and smooth removal of the device from the vagina.
- Pulling the string causes the arms to fold slightly towards the midline, thereby 25 reducing its size, allowing for an easy and smooth removal of the device from the vagina.

The applicator serves for insertion of the device into the vagina (FIG 4), as is done when inserting a regular menstrual tampon. The device is kept within the wider part (26) that is
30 inserted into the vagina. When pushing the plunger (28), the device is pushed through the flower like opening (24), allowing for its immediate action once the applicator is

removed from the vagina. The string (32) is visible, protruding out of the opening of the plunger (30).

When the device is still within the applicator (FIG 5), its flexible arms (34) converge towards the midline, allowing for the small dimensions and its insertion via a small diameter applicator. After insertion (FIG 6), the flexible arms of the device gain their pre-intended tension, enlarge the diameter of the device (46) within the vagina (48), anchoring itself under the bladder (40) between the uterine cervix (36) and the pubic bone (38), supporting mid-urethra (42). The string protrudes out of the vaginal introitus (44), as with the regular menstrual tampon, allowing for removal.

The invention has in its basic concept the following features:

- Being a disposable device.
- Insertion of the device is always with an applicator.
- Easy & comfortable insertion and removal.
- Being comfortable to wear.
- Being hygiene & odorless
- Being a familiar procedure to most female patients – as inserting a menstrual tampon.
- Being inserted by the patient herself, in a no-self-touch technique, with a disposable inserter.
- Being removed by the patient herself, in a no-self-touch technique, with the device collapsing and becoming of small size for painless removal.
- Being of high availability, easy to get everywhere, sold as an Over the Counter (OTC) device.
- Being of low cost.
- Having complete confidentiality, as with the use of menstrual tampons.
- Having the ability to be removed instantly when needed.
- No blockage of vaginal discharge.

Alternative embodiments of the invention.

- It may be manufactured in different sizes
- It may be made of many flexible materials, such as silicone, polyurethane, etc.

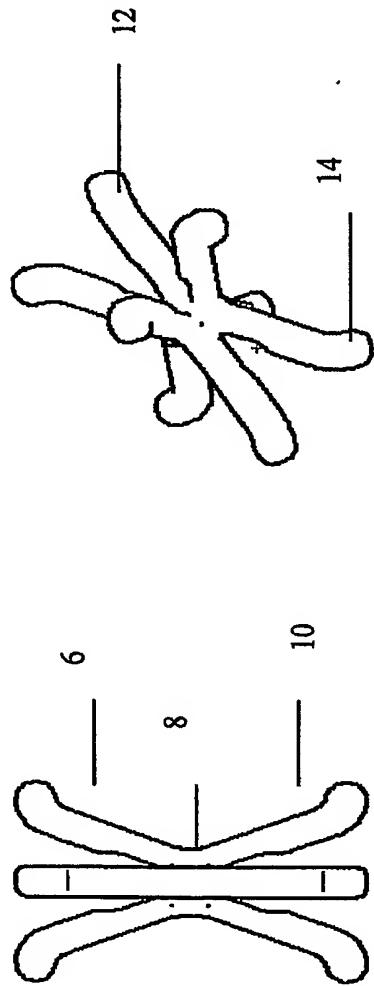


FIG. 1A

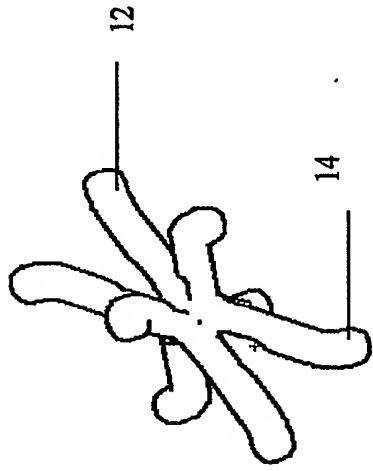


FIG. 1B

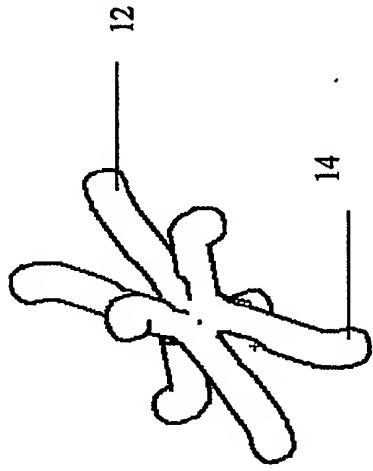


FIG. 1C

A disposable device for treatment & prevention of female urinary incontinence during physical activity
Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

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FIG. 2A

A-A
15

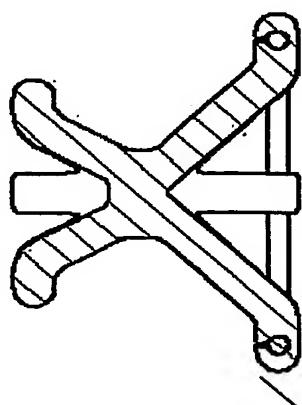


FIG. 2B

A-A
13

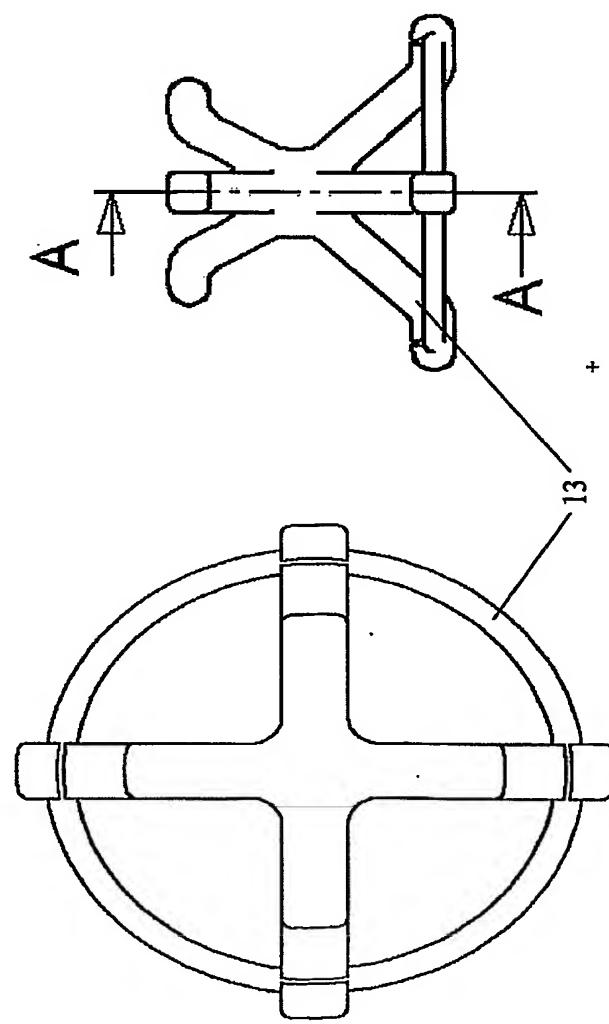


FIG. 2C

A disposable device for treatment & prevention of female urinary incontinence during physical activity
Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

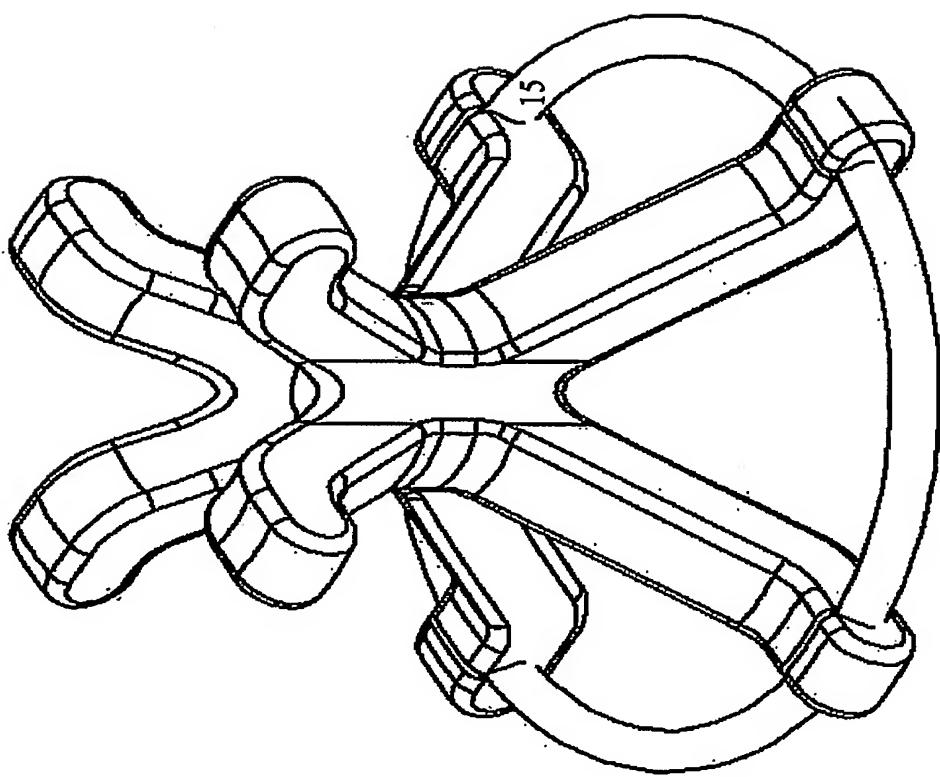


FIG. 2D

13

A disposable device for treatment & prevention of female urinary incontinence during physical activity
Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

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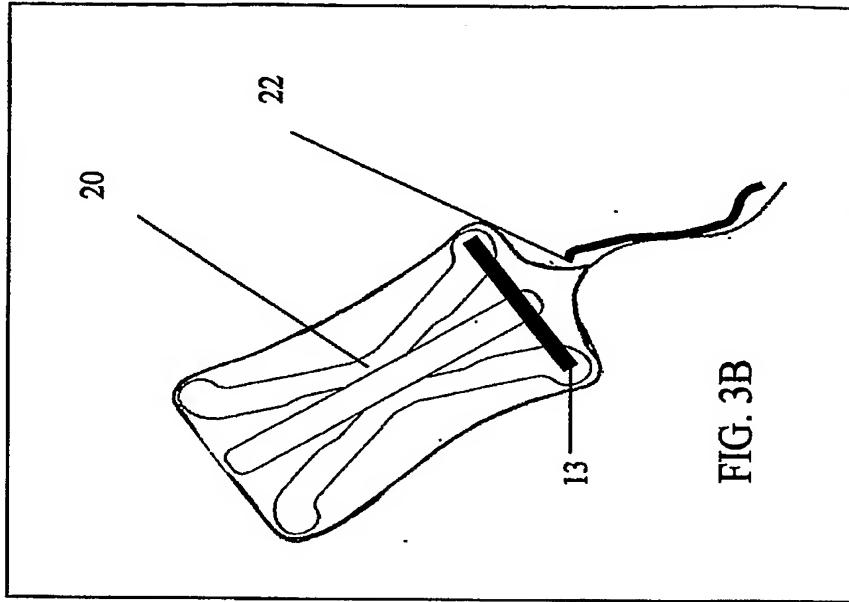


FIG. 3B

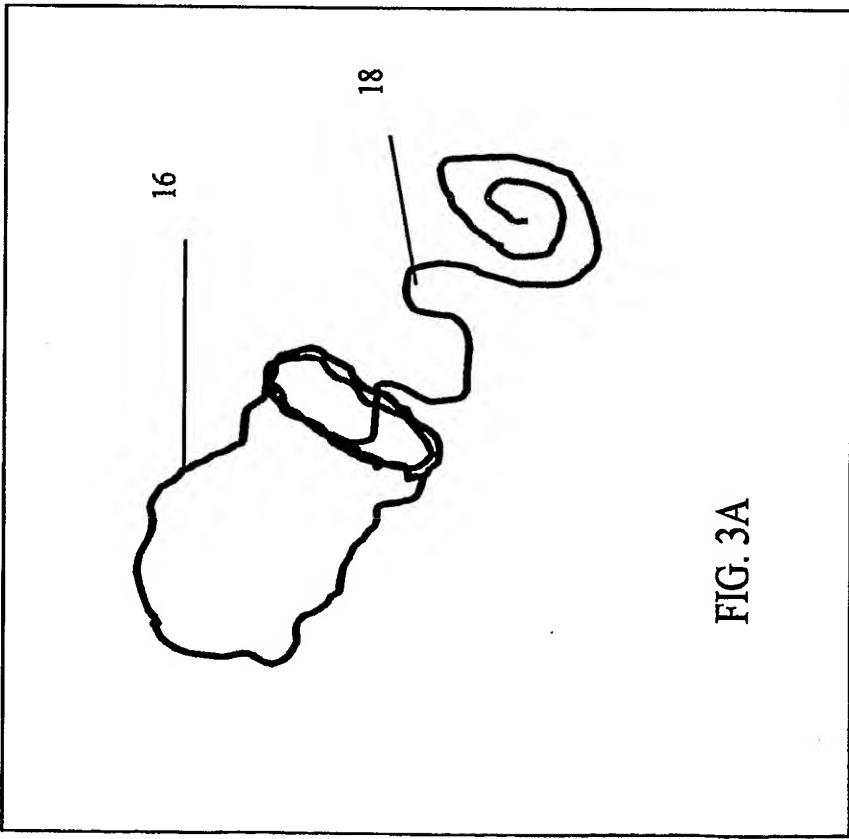


FIG. 3A

A disposable device for treatment & prevention of female urinary incontinence during physical activity
Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

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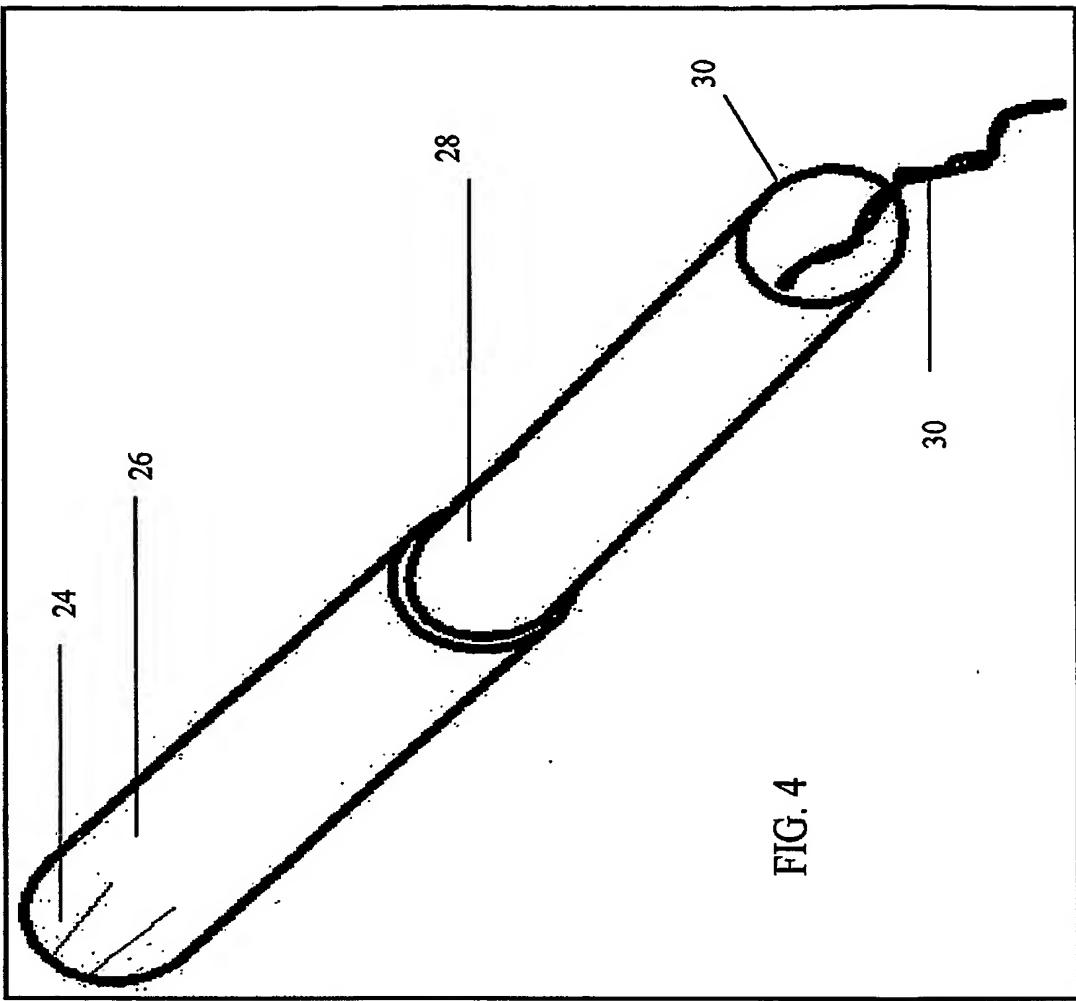


FIG. 4

A disposable device for treatment & prevention of female urinary incontinence during physical activity

Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

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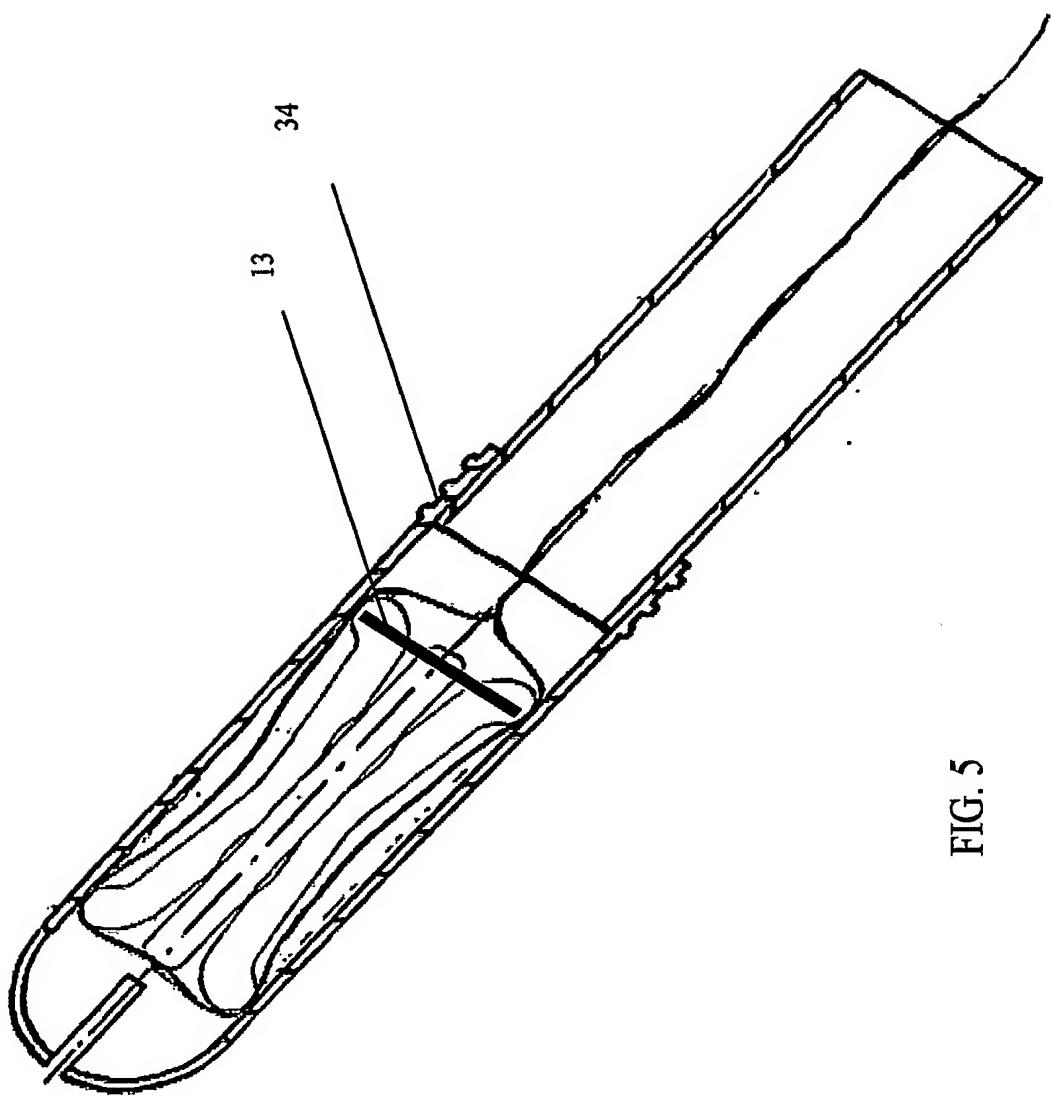


FIG. 5

A disposable device for treatment & prevention of female urinary incontinence during physical activity
Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist

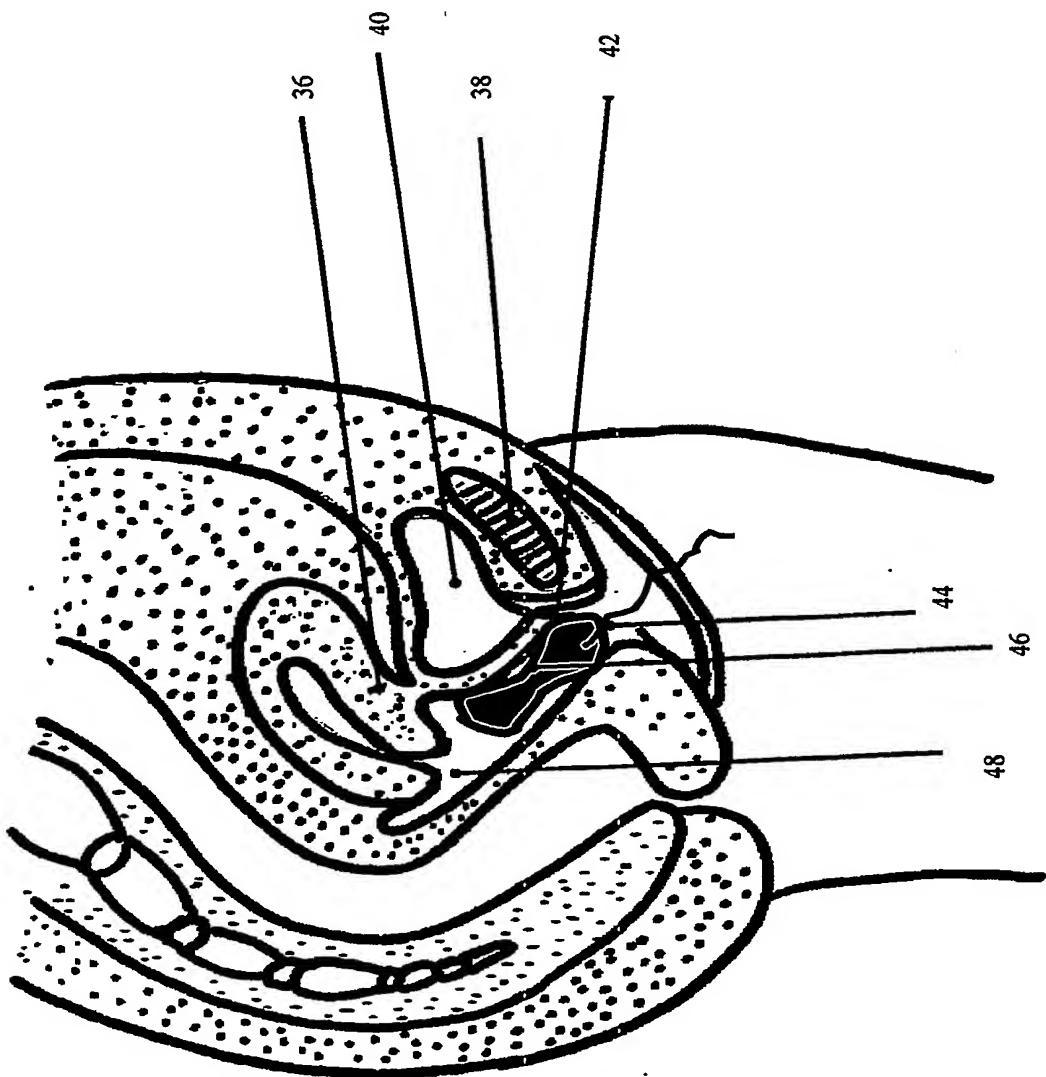


FIG. 6

A disposable device for treatment & prevention of female urinary incontinence during physical activity
Inventor: Dr Elan Ziv, MD OBGYN Urogynecologist